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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,889	12/21/2001	William M. Canfield	203512US77	5427

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EXAMINER	
FRONDA, CHRISTIAN L	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/023,889	CANFIELD, WILLIAM M.	
	Examiner	Art Unit	
	Christian L. Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *05/02/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-3 and 5-19 are pending and under consideration in this Office Action.

2. The objections of claims 7, 14, and 19 have been withdrawn in view of applicants' amendment to these claims filed 05/02/2005.

3. The rejection of claims 1-19 under 35 U.S.C. 112, second paragraph, as being indefinite has been withdrawn in view of in view of applicants' amendment to these claims filed 05/02/2005.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

4. Claims 1-3 and 5-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have amended the claims but have not presented arguments to traverse this rejection. However, the claims are rejected for the reasons as summarized below. The disclosed method for making human acid alpha glucosidase is only representative of a genus of methods for making lysosomal hydrolases having N-linked oligosaccharide side chains containing only core GlcNAc and mannose by: introducing and transforming a polynucleotide encoding a lysosomal hydrolase into a mammalian cell, culturing the mammalian cell in the presence of ricin, isolating the ricin resistant mammalian cell, culturing the ricin resistant mammalian cell in the presence of deoxymannojirimycin and kifunensine, and collecting the produced lysosomal hydrolases having N-linked oligosaccharide side chains containing only core GlcNAc and mannose.

In view of the these considerations, one of skill in the art would recognize that Applicant has failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicant was in possession of the claimed invention.

Claims 2, 3, and 5-19 which depend from claim 1 are also rejected because they do not correct the defect of claim 1.

Claim Rejections - 35 U.S.C. § 103

5. Claims 1-3, 5, 6, 18, and 19 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Martiniuk et al. (Biochem Biophys Res Commun. 2000 Oct 5;276(3):917-23) in view of the combined teachings of Stanley (Selection of lectin-resistant mutants of animal cells. In Methods in Enzymology, Vol. 96, 1983, pp 157-184), Bijvoet et al. (Hum Mol Genet. 1998 Oct;7(11):1815-24), Fuhrmann et al. (Nature (1984), 307(5953), 755-8), and Elbein et al. (J Biol Chem. 1990 Sep 15;265(26):15599-605).

Claims 7, 13, and 14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Martiniuk et al. in view of the combined teachings of Stanley, Bijvoet et al., Fuhrmann et al., and Elbein et al. as applied to claims 1-6, 18, and 19 above, and further in view of Glickman et al. (J Cell Biol. 1993 Oct;123(1):99-108).

Applicants' arguments filed 05/02/2005, have been fully considered but they are not persuasive. Applicants' position it that the claims provide introduction of a polynucleotide encoding a lysosomal hydrolase and then culturing the transfected cell with a lectin to obtain a lectin resistant cell which expresses the lysosomal hydrolase. Applicants argue that the order in which the steps are performed is important for producing a lysosomal hydroalse with reduced complex carbohydrates. Applicants argue that since transforming a lectin resistant cell line in order to express a non-native glycoprotein did not work, as suggested by the specification (see p. 4, lines 3-13), relative to the claimed method, then the present claims would not have been obvious.

The Examiner respectfully disagrees for reasons of record as supplemented below. As stated in the previous Office Action the modified Martiniuk et al. method contains all the claimed steps in the claimed order in which the claimed method is performed. The Examiner takes the position that the modified Martiniuk et al. method stated in the previous Office Action would inherently be able to produce the lysosomal hydroalse with high mannose oligosaccharides.

Since the Patent Office does not have the laboratory facilities for examining and comparing the modified Martiniuk et al. method to the claimed method, then the burden is on applicant to show that the modified Martiniuk et al. method stated in the previous Office Action is inoperative. See *In re Best*, 562 F.2d 1252, 195 USPQ 430(CCPA 1977).

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-19 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 10/023,890 in view of the combined teachings of prior art references of Martiniuk et al., Fuhrmann et al., and Elbein et al. This is a provisional obviousness-type double patenting rejection.

Applicants have not presented arguments to traverse this provisional rejection. Thus, the provisional rejection is maintained for reasons of record.

Conclusion

8. No claim is allowed.

9. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF

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